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Examiner:	Laura Bouchelle
Applicant:	Joseph P. McGurk
Title:	**SAFETY NEEDLE AND CATHETER ASSEMBLY**
Attorney Docket:	MDXVA-21US (formerly END-875)
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Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant request review of the August 9, 2006 rejections in the above-identified application (wherein the claims have been twice or more rejected). No amendments are being filed with this request, and it is being filed concurrently with a Notice of Appeal. The review is requested for the reasons set out hereinbelow.

REMARKS/ARGUMENTS FOR REVIEW

Claims 1-13 are pending and stand rejected under 35 U.S.C. 103(a). For purposes of this request, Applicant focuses on the independent claims, claims 1, 6, and 10, which stand rejected on the basis of Woehr et al (US 6287278) in view of Barr et al (US 3520292).[1]

[1] Applicant reserves comments on the dependent claims and/or additional arguments if the appeal proceeds.

Applicant's invention relates to catheter insertion devices wherein a sharp tip needle received within a catheter tube is used to insert the catheter tube into a patient's blood vessel after which the needle is to be removed. The device also includes a tip protector into which the sharp tip is to locate as it is pulled out of the catheter tube. In the present invention, the needle has a bent area near the sharp tip, such that the longitudinal axis of the tip section (i.e., the distal end) and the longitudinal axis of the main shaft of the needle (e.g., the proximal end) are offset. The present invention utilizes the bent area to prevent the needle from being pulled proximally out of the tip protector, such as by the bent area impacting against the back opening of the tip protector.

Woehr, the primary reference, also relates to a catheter insertion device with a tip protector. But Woehr's needle is straight, and has no bent section. In order to prevent the needle from being pulled proximally out of the tip protector, Woehr relies on (i) a tip protector that grips the surface of the needle shaft (e.g., FIGS. 1B and/or 4B), (ii) a tip protector with projections that enter slots or grooves in the needle's shaft (e.g., FIGS. 1B, 5B, and/or 13B), and/or (iii) bulges or crimps on the needle's shaft that impact against the tip protector (e.g., FIGS. 1D, 7E and/or 10B). In other words, Woehr already has a structure that prevents proximal pullout of the sharp tip from the tip protector, but as Examiner recognizes, Woehr does not have a bent area as claimed here by Applicant. So, Examiner looks to Barr. A fundamental question is "why"?

Why would it have been obvious to change the structure of the Woehr needle when Woehr already has a working design? There is no reason, making it painfully clear that Examiner simply went about to search for art showing a bent tip because Applicant's invention uses a bent tip, and then, for no reason, elected to substitute a bent needle for the straight needle of Woehr, a most explicit example of hindsight reconstruction if ever there was one.

Examiner's assertions about Woehr even raise question as to how carefully the disclosure of Woehr was reviewed. Examiner asserts, for example, that "Woehr discloses…a needle of constant diameter attached to a needle hub…", and then tells us simply to "See Abstract". To the contrary, the Abstract states that "[a] slot or bulge may be formed in the needle shaft" and virtually all of the embodiments of Woehr illustrate needles with discontinuities such as grooves, slots, bulges, or crimps that interact with the tip protector to prevent proximal pull-off and so define a needle that, in effect, is not of a constant diameter.

Moreover, Examiner does not state which embodiment(s) of Woehr are relied upon, even though there are at least ten embodiments illustrated therein. Examiner does not cite to any components of any embodiments to indicate what is considered to be the needle tip protector, the needle hub, and other claim limitations; a close enough review to provide such detail would have afforded Examiner the opportunity to see that Woehr already has structure to prevent needle tip proximal pull-out, and so is not in need of another, different solution. Instead, Examiner makes unsubstantiated statements (like saying that Woehr is a needle of constant diameter) and assumes the existence of various claim limitations.

Nor is any support given for the position that it would have been obvious to modify the needle of Woehr to have a bent area, nor whether that could even be done (absent Applicant's teachings). The tip protector of Woehr operates with an arm or a pair of arms that are biased against the surface of the needle and close down over the tip of the needle as the needle tip passes therebeyond. There is nothing in the art that even remotely suggests that a bend in the needle shaft to create offset sections of the needle as claimed herein would have been expected to work in such a needle tip protector. Applicant discovered that.

According to MPEP 706.02(j), Contents of a 35 U.S.C. 103 Rejection, "examiner should set forth in the Office action: (A) the relevant teachings of the prior art relied upon,

preferably with reference to the relevant column or page number(s) and line number(s) where appropriate...." Examiner does nothing of the sort here, nor can she as the reference itself undercuts the entire premise of the rejection.

The combination of Woehr and Barr does not achieve the claimed invention in any event. Examiner previously relied upon Bialecki in view of Barr. Bialecki had a crimp on the needle to stop the needle from being pulled out of the tip protector, just as do many of the embodiments of Woehr. However, when it became clear that Bialecki was no longer available as a reference, Examiner merely substituted Woehr. Examiner's reliance on Barr was misplaced before and is still misplaced for the same reasons already set out in Applicant's Response dated May 10, 2006 (hereinafter "Response"), on pages 7-10. By way of summary, merely because Barr happens to have a needle with a bent portion does not mean it teaches use of a bent needle to prevent proximal pull-out, nor any other purpose of a bent needle that would apply in the context of a catheter insertion device like that of either Woehr or Applicant's invention. In fact, Barr does not even have a needle tip protector (despite Examiner's unsupported statement to the contrary), nor does the bent portion thereof serve the purpose Examiner attributes to it. Despite Examiner's statement that the bent area of Barr "prevents the needle from moving longitudinally within the protector 12", element 12 is not a protector, but is actually an end wall that moves with the needle and is therefore merely the support for the needle. Indeed, Barr explicitly teaches away from such a purpose for the bent area thereof:

> For example, the cannula 14 need not have an intermediate obtuse portion as shown in the drawings. The cannula may be straight or have a U-shaped intermediate portion, or have other configurations common among the known cannulae. Likewise, the outer end 18 of the cannula need not be offset with respect to the longitudinal axis of holder 10. While the outer cannula end is preferably offset to facilitate insertion into the vein of the patient, it is to be understood that the outer cannula end may also be aligned axially with holder 10.

Col. 3, ll. 13-23. Such is hardly motivation to bend the needle of Woehr for purposes of its cooperation with the needle tip protector.

As evidenced above, there is clear error in the rejections. No prima facie case is made as there is no reason whatsoever to even consider modifying Woehr to solve a problem that Woehr already solves, nor does Barr provide the teachings ascribed to it by Examiner. Hence, Applicant respectfully asserts that the rejections are plainly in error, and Applicant should not be forced through the time and expense of a full-blown appeal.

Respectfully submitted,
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